REMARKS

The Office Action

Claims 1, 2, 4-13, 15-19, and 51-56 are pending. All claims stand rejected for lack of written description. Claims 1, 2, and 5 stand rejected for anticipation by Seggern (CA 2,281,602). Claims 1, 2, 4, 6, 7, 9-12, and 51 stand rejected for anticipation by Ranucci (Macromolecules, 1991 24:4554). Claims 1, 2, 4-7, 9-12, and 51-53 stand further rejected for obviousness over Ranucci in view of various secondary references.

Amendments to the Claims

Claims 1 and 5 have been amended to include the limitations of now cancelled claim 8. No new matter has been added.

The Application Is Entitled to Special Status

Applicants previously requested intervention of the SPE under M.P.E.P. § 707.02 in the Reply filed May 23, 2008, as the application has been pending for more than five years and has received more than three Office actions. Since that request, two additional non-final Office actions have been issued.

In the present application, the Office has raised an anticipation rejection over Seggern. This reference was cited by Applicants on April 30, 2007, and a Declaration of Prior Invention was submitted with respect to this reference on May 9, 2007 (supplemented on May 18, 2007). The Office does not appear to have considered this

Declaration prior to issuing the rejection. In addition, the Office has newly raised a written description rejection on similar grounds to a previous written description rejection raised in an Action mailed on October 6, 2005 and withdrawn in view of the Reply filed on January 4, 2006. Again, the Office does not appear to have considered previous prosecution prior to making the rejection. The claims were also previously allowed on January 29, 2007, and the Action dated January 30, 2009 indicated that the claims were in condition for allowance but for an issue of obviousness-type double patenting. Nonetheless, the Office has issued a seventh non-final Action.

Given the length of prosecution, the large number of non-final Office Actions, and the repetitive nature of these actions, Applicants respectfully request that the SPE carefully study this application and make every effort to bring it to final disposition and to treat it as "special," as stated in M.P.E.P. § 707.02.

Rejections under 35 U.S.C. § 112, second paragraph

The Office has rejected all claims for lack of written description. The basis of the rejection is the Office's belief that:

> [T]he genera of 'biomaterial' and of 'precursor component' compounds embraced by the claims are limitless to any biomaterial or precursor component, and the limited number of species in the instant disclosure do not provide support for description of the entire genus.

Applicants traverse the rejection.

M.P.E.P. § 2163.02 states that "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of

ordinary skill in the art to recognize that he or she invented what is claimed.'" (citations omitted). Furthermore, M.P.E.P. § 2163 states:

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.... If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, the adequate description requirement is met. (citations omitted)

Here, the Office has asserted without any evidentiary support that the species disclosed in the specification provide insufficient support. Applicants note, however, that a single disclosed species may be sufficient to adequately support a genus:

> disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered. (M.P.E.P. § 2163; citations omitted).

The instant claims meet these standards.

As an initial matter, the present claims are methods of manufacturing a biomaterial. The claimed methods are generally applicable in the manufacture of any biomaterial that can be made by the claimed process. Applicants need not describe every possible biomaterial that can be made using the claimed methods.

With respect to "precursor components," the Office alleges that the term is in general "limitless," the specification provides "no guidance ... for determining which 'precursor components' are useful for the method...," and that "only claim 54 limits the precursor compounds." None of these allegations is supported by the record.

In contrast to the Office's position, both independent claims 1 and 5 place limitations on the structure of the precursor components: each must include at least two strong nucleophiles (or amines) or at least two conjugated unsaturated bonds or groups. In addition, the precursor components must be capable of polymerizing through a self selective reaction between the strong nucleophile (or amine) and conjugated unsaturated bond or conjugated unsaturated group by nucleophilic addition. Furthermore, as amended, one of the precursor components must include at least three strong nucleophiles (or amines) or at least three conjugated unsaturated bonds or groups. These limitations are not merely functional but instead place constraints on the types of chemical compounds that can be employed. Nothing more is required to define these precursor components, as the invention is to a method of polymerizing compounds having specific reactive groups.

In addition and in contrast to the Office's assertion, Applicants provide numerous examples of possible precursor components for use in the claimed methods, including oligomers, polymers, biosynthetic proteins or peptides, naturally occurring peptides or proteins, processed naturally occurring peptides or proteins, and polysaccharides (page 3, lines 12-14; claim 2). Each of these general classes of compounds is well known to one skilled in the art. Further examples of precursor components include poly(ethylene glycol), poly(ethylene oxide), poly(vinyl alcohol), poly(ethylene-co-vinyl alcohol), poly(acrylic acid), poly(ethylene-co-acrylic acid), poly(ethyloxazoline), poly(vinyl pyrrolidone), poly(ethylene-co-vinyl pyrrolidone), poly(maleic acid), poly(ethylene-co-

maleic acid), poly(acrylamide), and poly(ethylene oxide)-co-poly(propylene oxide) block copolymers (page 3, lines 14-18; claim 7). Additional hydrophilic polymers, proteins, biosynthetic proteins, and peptides, which can be used in precursor components, are described at pages 41-43. Numerous peptide sequences that may be employed are also provided, including those having an adhesion site, a growth factor binding site, or a protease binding site (see Table 1, page 44, Table 2, page 45, Table 3, page 46, Table 4, page 52, and Table 5, page 53; claim 9). The specification provides further exemplary precursor components at pages 28-30. Example 1 describes the synthesis of exemplary precursor components, and examples 2, 5, 8, 11, and 14 describe the actual synthesis of biomaterials according to the claimed methods. Applicants also provide an extensive list of reactive groups, both nucleophiles (pages 38-40) and conjugated unsaturated bonds or groups (pages 31-38), through which the precursors are linked. Applicants have also provided substantial guidance on the possible reactions between the two precursor components (pages 47-50). Since Applicants have provided representative examples of the precursors, their reactive components, and their manner of linkage, one skilled in the art would understand that Applicants have invented what is claimed.

In further contrast to the Office's assertions, claims 2, 4, 6, 7, 9, 11, 51-53, and 55-56, as well as claim 54, place limitations on the precursor components employed in the claimed methods. The limitations of these claims were not addressed by the Office in the action. Accordingly, there is no basis on the record for the rejection of these claims.

With respect to "biomaterial," the Office asserts that "biomaterial is limitless to any material." This position is also not supported by the record. As recited in the claims, a biomaterial is not any material, rather it is the product of the claimed methods, i.e., the reaction product of the two precursor compounds. As explicitly defined by the claims, the biomaterial must include the residue of the self selective reaction of a strong nucleophile (or amine) and a conjugated unsaturated bond or group. The extensive teachings of the specification on the various precursor components that can be employed in making a biomaterial are described above. In particular, as noted, examples 2, 5, 8, 11, and 14 describe the actual synthesis of biomaterials according to the claimed methods. The specification also states that a biomaterial "is intended for contact with the body;" therefore, the biomaterial must be compatible with the surface of the body or when within the body. The definition is thus not purely functional, as it limits the properties, and thus chemical structure, of the biomaterial formed. Since Applicants have provided representative examples of biomaterials and precursors thereof, one skilled in the art would understand that Applicants have invented what is claimed. This basis of the rejection may also be withdrawn.

Applicants also note the Office's assertion that "DNA is embraced by the genus of biomolecules, but it clearly does not include any acrylate or thiol groups and Applicant has not provided any guidance for producing DNA with the claimed method; this level of disclosure is insufficient." The relevance of this position to a written description rejection is unclear. As discussed, the claimed methods do not result in the production of

any and all "biomolecules." Instead, the methods combine at least two precursor components to produce a biomaterial. As noted by the Office, native DNA does not include either a thiol or acrylate; thus, unmodified, naturally occurring DNA cannot be employed as a precursor component in the claimed methods. Applicants, however, need not describe how to use molecules that are not encompassed by the claims. It is noted, however, that covalent modification of DNA is known in the art, and a modified DNA including the strong nucleophile or conjugated unsaturated bond or group required by the claims could be employed. This final basis of the rejection may also be withdrawn.

Rejections under 35 U.S.C. §§ 102 and 103

The Office has indicated that claim 8 is neither anticipated by the cited references nor obvious over the cited references. Without agreeing with the Office's interpretation of the references, Applicants have amended independent claims 1 and 5 to incorporate the limitations of now cancelled claim 8. The rejections over the cited art are now moot. Applicants reserve the right to address the assertions made by the Office with respect to the cited references in the future, if necessary, and reserve the right to pursue the cancelled subject in this or a continuing application.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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